NDA 20-676/S-004

Bristol-Myers Squibb Company
Attention: Mr. Alan Skupp
Director, Regulatory Affairs
1350 Liberty Avenue
Hillside, New Jersey 07207

Dear Mr. Skupp:

Please refer to your supplemental new drug application dated May 30, 2001, received May 31, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for 1-Day® (Tioconazole Ointment 6.5% Vaginal Antifungal).

We acknowledge receipt of your submissions dated May 30, and July 27, 2001 (fax).

This supplemental new drug application provides for trade name and labeling format changes for the prefilled applicator drug product.

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text and with the minor editorial revisions listed below. Accordingly, these supplemental applications are approved effective on the date of this letter.

1. In the Drug Facts panel, change the heading ***"Active ingredients"*** to ***"Active ingredient".***
2. In the Drug Facts panel under ***Other information,*** replace the period with a semi-colon between the words "treatment" and "most" in the first bullet to read "this product is a 1-dose treatment; most women do not experience complete relief of their symptoms in just one day."
3. In the pouch label, replace the period (or comma) between the words "treatment" and "most" in the first bullet in *Other information* with a semi-colon to read "this product is a 1-dose treatment; most women do not experience complete relief of their symptoms in just one day."

The Agency is developing class labeling for all OTC vaginal antifungal products. When the guidance is finalized, we recommend that you draft the labeling for this product according to the format used in the Agency's final guidance document.

The final printed labeling (FPL) must be identical to the enclosed labeling with the minor editorial revisions listed above (pouch and carton labels) and must be formatted in accordance with the requirements of 21 CFR 201.66.

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory* Submissions in *Electronic Format - NDA* (January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-676/S-004." Approval of this submission by FDA is not required before the labeling is used. .

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit the copies to this Division.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

Please submit one market package of the drug product when it is available. We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Daniel P. Keravich, R.Ph., M.S., M.B.A., Regulatory Health Project Manager, at 301-827-2248.

Sincerely,

Linda M. Katz., M.D. M.P.H.
Deputy Director
Division of Over-the-Counter Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research